TITLE 71 INDIANA HORSE RACING COMMISSION

Emergency Rule LSA Document #14-143(E)

DIGEST

Adds 71 IAC 1-1-94.1 and 71 IAC 1.5-1-94.1 regarding the definition of sample for standardbred and flat racing. Amends 71 IAC 8-1-4.1 and 71 IAC 8.5-1-4.1 regarding nonsteroidal anti-inflammatory drugs. Amends 71 IAC 8-1-4.2 and 71 IAC 8.5-1-4.2 regarding threshold levels. Adds 71 IAC 8-1-7.1 and 71 IAC 8.5-1-7.1 regarding multiple medication violations. Amends 71 IAC 8-1-8 and 71 IAC 8.5-1-8 regarding anabolic steroids. Amends 71 IAC 8-3-5 and 71 IAC 8.5-2-5 regarding out of competition testing. Amends 71 IAC 8-6-2 and 71 IAC 8.5-5-2 regarding prohibited practices. Repeals 71 IAC 8-1-5.7 and 71 IAC 8.5-1-5.6. Effective May 15, 2014.

71 IAC 1-1-94.1; 71 IAC 1.5-1-94.1; 71 IAC 8-1-4.1; 71 IAC 8-1-4.2; 71 IAC 8-1-5.7; 71 IAC 8-1-7.1; 71 IAC 8-1-8; 71 IAC 8-3-5; 71 IAC 8-6-2; 71 IAC 8.5-1-4.1; 71 IAC 8.5-1-4.2; 71 IAC 8.5-1-5.6; 71 IAC 8.5-1-7.1; 71 IAC 8.5-1-8; 71 IAC 8.5-2-5; 71 IAC 8.5-5-2

SECTION 1. 71 IAC 1-1-94.1 IS ADDED TO READ AS FOLLOWS:

71 IAC 1-1-94.1 "Sample" defined

Authority: IC 4-31-2-23; IC 4-31-3-9

Affected: IC 4-31-12

Sec. 94.1. "Sample", when used in the context of being removed from or collected from a horse, means any amount of urine, saliva, blood, or other acceptable specimen derived from a horse. Any cleared samples may be used for research and/or investigative purposes by the commission.

(Indiana Horse Racing Commission; <u>71 IAC 1-1-94.1</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 2. 71 IAC 1.5-1-94.1 IS ADDED TO READ AS FOLLOWS:

71 IAC 1.5-1-94.1 "Sample" defined

Authority: IC 4-31-2-23; IC 4-31-3-9

Affected: IC 4-31-12

Sec. 94.1. "Sample", when used in the context of being removed from or collected from a horse, means any amount of urine, saliva, blood, or other acceptable specimen derived from a horse. Any cleared samples may be used for research and/or investigative purposes by the commission.

(Indiana Horse Racing Commission; <u>71 IAC 1.5-1-94.1</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 3. 71 IAC 8-1-4.1 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8-1-4.1 Nonsteroidal anti-inflammatory drugs (NSAIDs)

Authority: <u>IC 4-31-3-9</u> Affected: <u>IC 4-31-12</u>

- Sec. 4.1. (a) The use of one (1) of three (3) approved NSAIDs shall be permitted under the following conditions:
 - (1) Not to exceed the following permitted serum or plasma threshold concentrations which are consistent with administration by a single intravenous injection at the recommended labeled doses at least twenty-four (24) hours before the post time for the race in which the horse is entered:
 - (A) Phenylbutazone 2 micrograms per milliliter.
 - (B) Flunixin 20 nanograms per milliliter.
 - (C) Ketoprofen 10 nanograms per milliliter.

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- (b) These or any other NSAID are prohibited to be administered within the twenty-four (24) hours before post time for of the race in which the horse is entered.
- (c) The presence of more than one (1) of the three (3) approved NSAIDs, NSAID, with the exception exceptions of phenylbutazone in a concentration below 0.5 microgram 0.3 micrograms per milliliter of serum or plasma or any unapproved NSAID flunixin in a concentration below 3.0 nanograms per milliliter, in the post-race serum or plasma sample is not permitted. The use of all but one (1) of the approved NSAIDs shall be discontinued at least forty-eight (48) hours before the post time for the race in which the horse is entered.

(Indiana Horse Racing Commission; <u>71 IAC 8-1-4.1</u>; emergency rule filed Jul 28, 2006, 11:22 a.m.: <u>20060816-IR-071060279ERA</u>, eff Sep 1, 2006; emergency rule filed Jan 25, 2012, 12:20 p.m.: <u>20120201-IR-071120056ERA</u>; readopted filed Nov 26, 2013, 11:25 a.m.: <u>20131225-IR-071130345RFA</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 4. 71 IAC 8-1-4.2 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8-1-4.2 Threshold levels

- Sec. 4.2. The official blood (serum or plasma) sample and urine samples may contain the following drug substances, only the following therapeutic medications, their metabolites or analogues, analogues, and shall not exceed the threshold concentrations specified in this rule:
 - (1) The use of clenbuterol shall be permitted under the following conditions: Not to exceed twenty-five (25) picograms per milliliter of clenbuterol (or its metabolites) in serum or plasma.
 - (2) The use of firocoxib shall be permitted under the following conditions: Not to exceed forty (40) nanograms per milliliter of firocoxib (or its metabolites) in serum or plasma.
 - (3) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO (or its metabolites) in serum or plasma which allows for topical administration of DMSO in accordance with section 1.5 of this rule.
 - (1) The use of acepromazine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of the metabolite, 2-(1-hydroxyethyl) promazine sulfoxide (HEPS), in urine.
 - (2) The use of betamethasone shall be permitted under the following conditions: Not to exceed ten (10) picograms per milliliter of betamethasone in serum or plasma.
 - (3) The use of butorphanol shall be permitted under the following conditions: Not to exceed three hundred (300) nanograms per milliliter of total (free and conjugated) butorphanol in urine or two (2) nanograms per milliliter of free butorphanol in serum or plasma.
 - (4) The use of clenbuterol shall be permitted under the following conditions: Not to exceed one hundred forty (140) picograms per milliliter clenbuterol in urine or the limit of detection (LOD) in serum or plasma.
 - (5) The use of dantrolene shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of 5-hydroxydantrolene in serum or plasma.
 - (6) The use of detomidine shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of carboxydetomidine in urine or the LOD for detomidine in serum or plasma.
 - (7) The use of dexamethasone shall be permitted under the following conditions: Not to exceed five (5) picograms per milliliter of dexamethasone in plasma or serum.
 - (8) The use of diclofenac shall be permitted under the following conditions: Not to exceed five (5) nanograms per milliliter of diclofenac in plasma or serum.
 - (9) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO in serum or plasma.
 - (10) The use of firocoxib shall be permitted under the following conditions: Not to exceed twenty (20) nanograms per milliliter of firocoxib in serum or plasma.
 - (11) The use of glycopyrrolate shall be permitted under the following conditions: Not to exceed three (3) picograms per milliliter of glycopyrrolate in serum or plasma.
 - (12) The use of lidocaine shall be permitted under the following conditions: Not to exceed twenty (20) picograms per milliliter of total 3-hydroxylidocaine in serum or plasma.
 - (13) The use of mepivacaine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of total 3-hydroxymepivacaine in urine or the LOD of mepivacaine in serum or

plasma.

- (14) The use of methocarbamol shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of methocarbamol in serum or plasma.
- (15) The use of methylprednisolone shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of methylprednisolone in serum or plasma.
- (16) The use of omeprazole shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of omeprazole sulfide in urine.
- (17) The use of prednisolone shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of prednisolone in serum or plasma.
- (18) The use of procaine penicillin shall be permitted under the following conditions:
 - (A) Not to exceed twenty-five (25) nanograms per milliliter of procaine in serum or plasma, and
 - (B) Administration of procaine penicillin must be reported to the official veterinarian at the time of administration, and
 - (C) Procaine penicillin must not be administered after the horse is entered to race, and
 - (D) Mandatory surveillance of the horse must occur for the six (6) hours immediately preceding the race for which the horse is entered by association security at the owner's expense.
- (19) The use of triamcinolone acetonide shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of triamcinolone acetonide in serum or plasma.
- (20) The use of xylazine shall be permitted under the following conditions: Not to exceed one-hundredth (.01) of a nanogram per milliliter of xylazine in serum or plasma.

(Indiana Horse Racing Commission; <u>71 IAC 8-1-4.2</u>; emergency rule filed Jan 25, 2012, 12:20 p.m.: <u>20120201-IR-071120056ERA</u>; emergency rule filed Feb 8, 2012, 12:01 p.m.: <u>20120215-IR-071120072ERA</u>; emergency rule filed Apr 3, 2013, 10:37 a.m.: <u>20130410-IR-071130133ERA</u>; readopted filed Nov 26, 2013, 11:25 a.m.: <u>20131225-IR-071130345RFA</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 5. 71 IAC 8-1-7.1 IS ADDED TO READ AS FOLLOWS:

71 IAC 8-1-7.1 Multiple medication violations

Authority: <u>IC 4-31-3-9</u> Affected: <u>IC 4-31-12</u>

Sec. 7.1. (a) A trainer who receives a penalty for a medication violation based upon a horse testing positive for a Class 1-5 medication with Penalty Class A-D, as provided in the Uniform Classification Guidelines of Foreign Substances and Recommended Penalties and Model Rule as revised by the ARCI in August 1996 and any other subsequent revision effective after said date, which are incorporated by reference herein, may be assigned points based upon the medication's ARCI Penalty Guidelines as follows:

Class	Points if Controlled Therapeutic Substance	Points if Noncontrolled Substance
Class A	N/A	6
Class B	2	4
Class C	1	2
Class D	1/2	1

- (b) The points assigned to a medication violation shall be included in the judges or commission ruling. Such ruling shall determine, in the case of multiple positive tests as described in paragraph [sic] (d), whether they shall thereafter constitute a single violation. The ruling shall be posted on the official website of the ARCI. If an appeal is pending, that fact shall be noted in the ruling. No points shall be applied until a final adjudication of the enforcement of any such violation.
- (c) Once all appeals are waived or exhausted, the points shall immediately become part of the trainer's official ARCI record and shall then subject the trainer to the mandatory enhanced penalties by the judges or the commission as provided in this section.
- (d) Multiple positive tests for the same medication incurred by a trainer prior to delivery of official notice by the commission may be treated as a single violation.

- (e) The official ARCI record shall constitute prima facie evidence of a trainer's past record of violations and cumulative points. Nothing in this section shall be construed to confer upon a trainer the right to appeal a violation for which all remedies have been exhausted or for which the appeal time has expired.
- (f) The judges or commission shall include all points for violations in all racing jurisdictions as contained in the trainer's official ARCI record when determining whether the enhancements provided in this regulation shall be imposed.
- (g) In addition to the penalty for the underlying offense, the following enhancements may be imposed upon a licensed trainer based upon the cumulative points contained in the trainer's official ARCI record:

Points	Suspension in Days
3-5.5	30
6-8.5	60
9-10.5	180
11 or more	360

These points are intended to be an additional uniform penalty when the licensee:

- (1) has more than one violation for the relevant time period; and
- (2) exceeds the permissible number of points.
- (h) The suspension periods in [sic] (g) shall run consecutive to any suspension imposed for the underlying offense.
- (i) The judges' or commission's ruling shall distinguish between the penalty for the underlying offense and the enhancement based upon the trainer's cumulative points.

(Indiana Horse Racing Commission; <u>71 IAC 8-1-7.1</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 6. 71 IAC 8-1-8 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8-1-8 Anabolic steroids

Authority: <u>IC 4-31-3-9</u> Affected: IC 4-31-12

- Sec. 8. (a) No AAS (androgenic-anabolic steroid) shall be permitted in test samples collected from racing horses except for residues **endogenous concentrations** of the major metabolite of stanozolol, nandrolone, and the naturally occurring substances boldenone, **nandrolone**, and testosterone at concentrations less than the indicated thresholds.
- (b) Concentrations of these AAS shall not exceed the following urine threshold concentrations for total (i.e., free drug or metabolite and drug or metabolite liberated from its conjugates) **steroid:**
 - (1) 16# hydroxystanozolol (metabolite of stanozolol (Winstrol)) one (1) ng/ml in urine for all horses regardless of sex.
 - (2) (1) Boldenone: (Equipoise® is the undecylenate ester of boldenone)
 - (A) In male horse horses other than geldings fifteen (15) ng/ml in of urine. No boldenone shall be permitted in geldings or female horses.
 - (B) In geldings, fillies, and mares one (1) ng/mL of urine.
 - (3) (2) Nandrolone: (Durabolin® is the phenylpropionate ester and Deca-Durabolin® is the decanoate ester):

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- (A) In geldings one (1) ng/ml in of urine.
- (B) In fillies and mares one (1) ng/ml in of urine.
- (C) In male horses other than geldings forty-five (45) ng/ml of nandrolone metabolite,
- 5#-oestrane-3#,17#-diol in 5#-estrane-3#,17#-diol of urine.
- (4) (3) Testosterone:
 - (A) In geldings twenty (20) ng/ml in of urine.
 - (B) In fillies and mares fifty-five (55) ng/ml of urine, unless in foal.

- (C) In male horses other than geldings minimum thresholds will not apply.
- (c) Concentrations of these AAS shall not exceed the following free (i.e., not conjugated) steroid concentrations in plasma or serum:
 - (1) Boldenone: For all horses a confirmatory threshold not greater than 25 pg/ml shall apply.
 - (2) Nandrolone:
 - (A) In geldings, fillies, and mares a confirmatory threshold not greater than 25 pg/ml shall apply.
 - (B) In male horses other than geldings nandrolone shall be tested for in urine only.
 - (3) Testosterone:
 - (A) In geldings, fillies, and mares a confirmatory threshold not greater than 25 pg/ml.
 - (B) In male horses other than geldings minimum thresholds will not apply.
 - (e) (d) All other AAS are prohibited in racing horses.
 - (d) Post-race urine samples collected from intact males must be identified to the laboratory.
 - (e) The sex of the horse must be identified to the laboratory for all samples designated for AAS testing.
- (e) Any horse to which an anabolic steroid has been administered in order to assist in the recovery from illness or injury may be placed on the veterinarian's list in order to monitor the concentration of the drug or metabolite in urine. After the concentration has fallen below the designated threshold for the administered AAS, the horse is eligible to be removed from the list.
 - (f) Implementation of this rule shall commence April 1, 2008.
- (g) During the first ninety (90) calendar days of the first race meet beginning after the implementation date, no positive test establishing the presence of an anabolic steroid shall be considered a violation of this rule and, accordingly, shall not result in a penalty, disqualification, or a forfeiture of any purse, trophy, or award. Trainers shall be notified of any positive test during the ninety (90) day grace period.
- (f) A trainer may request that a horse be placed on the veterinarian's list due to medically necessary treatment with AAS. The horse shall remain on the veterinarian's list:
 - (1) for 365 days;
 - (2) until the concentration of the drug or metabolite in urine or blood has fallen below the designated threshold for the administered AAS; or
 - (3) until the concentration of the drug or metabolite in urine or blood has fallen below the limit of detection for AAS that do not have a designated threshold, whichever is longer.

(Indiana Horse Racing Commission; 71 IAC 8-1-8; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed May 12, 2008, 1:29 p.m.: 20080521-IR-071080353ERA; readopted filed Nov 26, 2013, 11:25 a.m.: 20131225-IR-071130345RFA; emergency rule filed May 7, 2014, 2:27 p.m.: 20140514-IR-071140143ERA, eff May 15, 2014)

SECTION 7. 71 IAC 8-3-5 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8-3-5 Out of competition testing

Authority: <u>IC 4-31-3-9</u> Affected: <u>IC 4-31-12</u>

Sec. 5. (a) Any horse eligible to race in Indiana under this subsection is subject to testing without advance notice for prohibited substances, practices, and procedures as specified in subsection (f), while the horse is located on the grounds of a racetrack under the jurisdiction of the commission, or stabled off association grounds while under the care or control of trainer or owner licensed by the commission under the restrictions listed in subsection (e). A horse is eligible to race in Indiana if it is listed:

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- (1) on an owner's or trainer's license application; or
- (2) a stall application, nomination list; or
- (3) on the horse sign-in sheet at any time during the meet; or
- (4) has raced at any Indiana race meet during the calendar year.

A horse shall be presumed eligible if it is a racing breed, at least two (2) years old and an Indiana bred or sired horse. The owner of such an Indiana bred or sired horse may render the horse ineligible for the testing as described in this regulation by indicating in writing the Indiana bred or sired horse is not intended to race in Indiana, pursuant to subsection (b) below provided that the owner of such an Indiana bred or sired horse provides such written notice to the office of the commission thirty (30) days before the horse turns two (2) years old or within thirty (30) days after the owner acquires the horse. In this event, the horse shall be deemed ineligible for racing in Indiana as provided for in subsection (b) below.

- (b) If a horse to be tested is not covered under subsection (a), the executive director or judges may nevertheless test any such horse as eligible to race in Indiana for prohibited substances, practices, and procedures specified in subsection (f), unless the owner or trainer or other authorized representative or designee of such horse immediately represents in writing that the horse is not intended to be, and will not be, raced in Indiana for a minimum of three hundred sixty-five (365) days. If the owner, trainer, or other authorized representative or designee so represents, the horse shall be deemed ineligible for racing in Indiana for no less than three hundred sixty-five (365) days from that date. This three hundred sixty-five (365) day ineligibility to race in Indiana shall follow the horse even if sold or transferred to another owner or trainer. An owner or trainer may, however, consent to the collection of a sample from a horse selected for testing under this rule, even if the horse is not presently intended to be raced in Indiana, and if such horse tests negative, it will remain eligible to race in Indiana.
- (c) The executive director or judges may order any horse of a licensed trainer to report to a track under the jurisdiction of the commission for out of competition testing. The trainer is responsible to have the horse or horses available at the designated time and location. In the event that a horse is ordered to report to a track pursuant to the authority granted by this subsection, a licensed trainer is entitled to reimbursement by the commission for mileage (at the current rate paid by the state of Indiana as specified in the current Indiana financial management circular) to and from the location where the horse was stabled when the horse was ordered to report to the track. Under no circumstances will a trainer be entitled to reimbursement for mileage in excess of the actual mileage to the track from the place where the horse was stabled when ordered to report and from the track to the place where the horse is first stabled following the testing. The trainer is not entitled to receive reimbursement from the commission for any other expense relating to any order under this subsection to report to a track for out-of-competition testing.
- (d) The official veterinarian, a licensed veterinarian authorized by the commission, a veterinary technician under the direct supervision of the official veterinarian, or a licensed veterinarian authorized by the commission may take a urine, blood, or hair sample from a horse for testing as provided for in this section.
- (e) Unless sample collection occurs on the grounds of a racetrack or other location within Indiana under the commission's jurisdiction, the commission's representatives must arrive for the taking of blood, urine, or hair samples from an eligible horse as defined in subsections [subsection] (a) or (b), only between the hours of 7:00 a.m. and noon, after announcing their presence at the premises where the horse(s) to be tested is (are) located and showing their credentials to collect samples from the horse(s) selected for testing for prohibited substances, practices, and procedures as specified in subsection (f). The commission's representatives or designees will request to meet with the trainer or owner of the selected horse(s). If either neither is available, the collection will be deferred until the trainer and/or owner, or their representative or designee, becomes reasonably available, but the collection must occur not later than one (1) hour after the commission's designee arrives at the premises in the case of an eligible horse under subsection (a), and not later than two (2) hours in the case of an eligible horse under subsection (b). If the collection does not occur within the time provided for in this subsection, any horse that would have been subject to testing and eligible to race in Indiana will be deemed to be ineligible for racing in Indiana pursuant to the provisions of subsections (a) and (b). In addition, the owner and/or trainer of the horses may be subject to any other sanctions allowed by Indiana law and regulations, including, but not limited to, a fine, suspension, and/or summary suspension. It is a defense to any action brought against an owner and/or trainer for sanctions or as a result of any declaration a horse is ineligible because the sample collection did not occur within the time provided for by this subsection that good cause existed that prohibited the owner, trainer, and/or their representative or designee from complying with the time limits set forth in this subsection. The owner, trainer, and/or their representative or designee has the burden of proving the good cause defense by a preponderance of

the evidence.

- (f) Prohibited substances, practices, and procedures are defined as the following:
- (1) blood doping agents including, but not limited to, erythropoietin (EPO), darbepoetin, Oxyglobin, Hemopure, Aranesp, or any substance that abnormally enhances the oxygenation of body tissues;
- (2) gene doping agents or the nontherapeutic use of genes, genetic elements, and/or cells that have the capacity to enhance athletic performance or produce analgesia;
- (3) naturally produced venoms, synthetic analogues of venoms, derivatives of venoms, or synthetic analogues of derivatives of venoms;
- (4) substances capable of producing a repartitioning effect that are not FDA-approved for use in horses, including, but not limited to, ractopamine, zilpaterol, or any similar agent;
- (5) AAS (androgenic-anabolic steroids) other than stanozolol, nandrolone, boldenone, testosterone, and metabolites thereof; endogenous concentrations of the naturally occurring substances as defined in 71 IAC 8-1-8 or AAS in a horse placed on the veterinarian's list in accordance with 71 IAC 8-1-8(f); and
- (6) the presence in a horse of any substance at anytime listed in subdivision (1), (2), (3), (4), or (5) in an eligible as defined in subsections (a) and (b) above is prohibited and is a violation of this rule.
- (g) The trainer and/or his/her designees shall cooperate with the official veterinarian or any licensed veterinarian or licensed veterinary technician authorized by the commission or any commission employee by:
 - (1) assisting in the immediate location and identification of the eligible horse selected for out of competition testing; and
 - (2) providing a stall or safe location to collect the samples.

The executive director or judges may summarily suspend, exclude, and/or otherwise penalize any trainer and/or other authorized representative or designee who does not fully cooperate with a commission employee or representative in assisting and identifying an eligible horse or providing a safe stall to collect samples in a timely fashion. If any such person is summarily suspended, excluded, or otherwise penalized, she/he shall be entitled to a hearing in accordance with Indiana law and regulations. A summary suspension, exclusion, or sanctions for failure to cooperate shall not issue, however, if a horseman meets his or her burden to establish the good cause defense set forth under subsection (e). This provision does not apply to an owner or trainer who timely provides written notice under subsection (a) or (b) that a horse sought to be tested is not intended to be raced in Indiana and thereby renders the horse ineligible pursuant to subsection (b).

- (h) The collection of blood, urine, or hair samples under this rule shall be divided in three (3) parts to be analyzed as follows:
 - (1) approved primary laboratory for screening;
 - (2) approved primary laboratory for confirmation; and
 - (3) approved laboratory for split sample testing as chosen by the owner or trainer.

The commission shall approve the laboratories for screening, confirmation, and split sample testing.

(i) In the absence of extraordinary mitigating circumstances, a minimum penalty of a ten (10) year suspension will be assessed for any violation of subsection (f)(1) and (f)(2) of this rule [subsection (f)(1) and (f)(2)]. The Association of Racing Commissioners International, Inc. Uniform Classification Guidelines for Foreign Substances and Recommended Penalties and Model Rule will be considered for violations of (f)(3), (f)(4), and (f)(5)] with additional penalties for any drug not FDA approved for use in horses.

(Indiana Horse Racing Commission; 71 IAC 8-3-5; emergency rule filed Jul 23, 2007, 9:16 a.m.: 20070808-IR-071070461ERA, eff Jul 18, 2007 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #07-461(E) was filed with the Publisher July 23, 2007.]; errata filed Aug 14, 2007, 1:28 p.m.: 20070829-IR-071070461ACA; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.: 20110309-IR-071110100ERA; emergency rule filed Sep 10, 2012, 2:01 p.m.: 20120912-IR-071120525ERA; emergency rule filed May 7, 2014, 2:27 p.m.: 20140514-IR-071140143ERA, eff May 15, 2014)

SECTION 8, 71 IAC 8-6-2 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8-6-2 Prohibited practices

Authority: IC 4-31-3-9 Affected: IC 4-31

Sec. 2. (a) The possession and/or use of a drug, substance, or medication, specified below, on the premises of a facility under the jurisdiction of the commission is prohibited. These drugs or substances include those which a recognized analytical method has not been developed to detect and confirm the administration of such substance, or the use of which may endanger the health and welfare of the horse or endanger the safety of the rider, or the use of which may adversely affect the integrity of racing:

- (1) Erythropoietin.
- (2) Darbepoietin.
- (2) Darbepoetin.
- (3) Oxyglobin.
- (4) Hemopure.
- (5) Snake venom.
- (6) Snail venom.
- (7) Ractopamine.
- (8) Zilpaterol.
- (b) The use of extracorporeal shock wave therapy or radial pulse wave therapy shall not be permitted unless the following conditions are met:
 - (1) Any treated horse shall not be permitted to race for a minimum of ten (10) days following treatment.
 - (2) The use of extracorporeal shock therapy or radial pulse wave therapy machines shall be limited to practicing veterinarians.
 - (3) Any extracorporeal shock therapy or radial pulse therapy machines on the association grounds must be registered with and approved by the commission or its designee before use.
 - (4) All extracorporeal shock therapy or radial pulse therapy treatments must be reported to the official veterinarian on the prescribed form not later than the time prescribed by the official veterinarian.
- (c) The possession and/or use of a drug, substance, or medication on the premises of a facility under the jurisdiction of the commission that has not been approved by the United States Food and Drug Administration (FDA) for any use (human or animal) is forbidden without prior permission of the commission. For purposes of this rule, the term "drug" is any substance, food or nonfood, that is used to treat, cure, mitigate, or prevent a disease, any nonfood substance that is intended to affect the structure or function of the animal, and includes any substance administered by injection **other than vaccines licensed by the USDA.**
- (d) While on the premises of a facility under the jurisdiction of the commission, veterinarians may only possess drugs, including compounds as discussed below in subsection (e), in amounts commensurate with the needs of horses with which the veterinarian has a veterinarian-client-patient relationship as that term is defined at 888 IAC 1.1-5-1(2).
- (e) Notwithstanding subsection (c), veterinarians may possess compounded drugs with the restrictions listed below. Compounding includes any manipulation of a drug beyond that stipulated on the drug label, including, but not limited to, mixing, diluting, concentrating, and/or creating oral suspensions or injectable solutions.
 - (1) Compounds may only be prescribed to or prepared for horses with which the veterinarian has a veterinarian-client-patient relationship;
 - (2) Compounded drugs may only be made from other FDA-approved drugs;
 - (3) Veterinarians may not possess compounds where there are FDA-approved, commercially available drugs that can appropriately treat the horse; and
 - (4) Compounded drugs must be in containers that meet the prescription labeling requirements in subsections (i) and (j).
- (f) The possession of any drug not approved by the FDA for distribution in the United States is prohibited, unless the veterinarian can show proof of prior authorization from the FDA Center for Veterinary Medicine that has been obtained on a single-patient basis only. The authorization must be maintained in the animal health record. A copy of the authorization must be available for immediate inspection.

- (g) Extra-label administration of drugs, including use for indication or at dosage levels, frequencies, or routes of administration other than those stated in the labeling, is permitted for FDA-approved drugs only. Extra-label use must meet the prescription labeling requirements in subsections (i) and (j).
- (h) A veterinarian shall not possess any drug that is not labeled pursuant to the requirements of subsection (i) or (j).
- (i) Drugs possessed by practicing veterinarians on the premises of a facility under the jurisdiction of the commission which have not yet been prescribed or dispensed to horses with which the veterinarian has a veterinarian-client-patient relationship must be affixed with the manufacturer's label, which must include:
 - (1) recommended or usual dosage;
 - (2) route for administration, if it is not for oral use;
 - (3) quantity or proportion of each active ingredient;
 - (4) names of inactive ingredients, if for other than oral use;
 - (5) an identifying lot or control number;
 - (6) manufacturer, packer, or distributor's name and address; and
 - (7) net quantity contents.

If any information as described herein is not included on the manufacturer's label, but instead is on the manufacturer's package insert, the package insert must be maintained on the veterinarian's truck.

- (j) When issuing a prescription for or dispensing a drug to a horse with which the veterinarian has a veterinarian-client-patient relationship, the veterinarian must affix or cause to be affixed a label which sets forth the following:
 - (1) Name and address of the veterinarian;
 - (2) Name and address of the client:
 - (3) Name of the horse;
 - (4) Date of prescription and/or dispensing of drug;
 - (5) Directions for use, including dose and duration directions, and number of refills;
 - (6) Name and quantity of the drug (or drug preparation, including compounds) prescribed or dispensed;
 - (7) For compounded drugs, the established name of each active ingredient; and
 - (8) Any necessary cautionary statements.
- (k) The practice, administration, or application of a treatment, procedure, therapy, or method identified below, which is performed on the premises of a facility under jurisdiction of the commission or in any horse scheduled to compete in a race under the jurisdiction of the commission and which may endanger the health and welfare of the horse or endanger the safety of the rider or driver, or the use of which may adversely affect the integrity of racing is prohibited: Intermittent hypoxic treatment by external device.

(Indiana Horse Racing Commission; 71 IAC 8-6-2; emergency rule filed Feb 21, 2003, 4:15 p.m.: 26 IR 2385; emergency rule filed Jan 21, 2004, 2:30 p.m.: 27 IR 1920; emergency rule filed Mar 10, 2006, 11:00 a.m.: 29 IR 2220; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.: 20110309-IR-071110100ERA; emergency rule filed May 7, 2014, 2:27 p.m.: 20140514-IR-071140143ERA, eff May 15, 2014)

SECTION 9. 71 IAC 8.5-1-4.1 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8.5-1-4.1 Nonsteroidal anti-inflammatory drugs (NSAIDs)

Authority: <u>IC 4-31-3-9</u> Affected: <u>IC 4-31-12</u>

Sec. 4.1. (a) The use of one (1) of three (3) approved NSAIDs shall be permitted under the following conditions:

(1) Not to exceed the following permitted serum or plasma threshold concentrations which are consistent with administration by a single intravenous injection at the recommended labeled dose at least twenty-four (24)

hours before the post time for the race in which the horse is entered:

- (A) Phenylbutazone 2 micrograms per milliliter.
- (B) Flunixin 20 nanograms per milliliter.
- (C) Ketoprofen 10 nanograms per milliliter.
- (b) These or any other NSAID are prohibited to be administered within the twenty-four (24) hours before the post time for of the race in which the horse is entered.
- (c) The presence of more than one (1) of the three (3) approved NSAIDs, NSAID, with the exception exceptions of phenylbutazone in a concentration below 0.5 microgram 0.3 micrograms per milliliter of serum or plasma or any unapproved NSAID or flunixin in a concentration below 3.0 nanograms per milliliter in the post-race serum or plasma sample is not permitted. The use of all but one (1) of the approved NSAIDs shall be discontinued at least forty-eight (48) hours before the post time for the race in which the horse is entered.

(Indiana Horse Racing Commission; <u>71 IAC 8.5-1-4.1</u>; emergency rule filed Jul 28, 2006, 11:22 a.m.: <u>20060816-IR-071060279ERA</u>, eff Sep 1, 2006; readopted filed Mar 23, 2007, 11:31 a.m.: <u>20070404-IR-071070030RFA</u>; emergency rule filed Jan 25, 2012, 12:20 p.m.: <u>20120201-IR-071120056ERA</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 10. 71 IAC 8.5-1-4.2 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8.5-1-4.2 Threshold levels

- Sec. 4.2. The official blood (serum or plasma) sample and urine samples may contain the following drug substances, their metabolites or analogs, only the following therapeutic medications, their metabolites or analogues, and shall not exceed the threshold concentrations specified in this rule:
 - (1) The use of clenbuterol shall be permitted under the following conditions:
 - (A) Not to exceed the following permitted serum or plasma threshold concentrations of clenbuterol (or its metabolites): Thoroughbred twenty-five (25) picograms per milliliter.
 - (B) Not to exceed the following permitted serum or plasma threshold concentrations of clenbuterol (or its metabolites): Quarter horse—two (2) picograms per milliliter.
 - (2) The use of firocoxib shall be permitted under the following conditions: Not to exceed forty (40) nanograms per milliliter of firocoxib (or its metabolites) in serum or plasma.
 - (3) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO (or its metabolites) in serum or plasma which allows for topical administration of DMSO in accordance with section 1.5 of this rule.
 - (1) The use of acepromazine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of the metabolite, 2-(1-hydroxyethyl) promazine sulfoxide (HEPS), in urine.
 - (2) The use of betamethasone shall be permitted under the following conditions: Not to exceed ten (10) picograms per milliliter of betamethasone in serum or plasma.
 - (3) The use of butorphanol shall be permitted under the following conditions: Not to exceed three hundred (300) nanograms per milliliter of total (free and conjugated) butorphanol in urine or two (2) nanograms per milliliter of free butorphanol in serum or plasma.
 - (4) The use of clenbuterol shall be permitted under the following conditions: Not to exceed one hundred forty (140) picograms per milliliter clenbuterol in urine or the limit of detection (LOD) in serum or plasma.
 - (5) The use of dantrolene shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of 5-hydroxydantrolene in serum or plasma.
 - (6) The use of detomidine shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of carboxydetomidine in urine or the LOD for detomidine in serum or plasma.
 - (7) The use of dexamethasone shall be permitted under the following conditions: Not to exceed five (5) picograms per milliliter of dexamethasone in plasma or serum.
 - (8) The use of diclofenac shall be permitted under the following conditions: Not to exceed five (5) nanograms per milliliter of diclofenac in plasma or serum.
 - (9) The use of dimethylsulfoxide (DMSO) shall be permitted under the following conditions: Not to exceed ten (10) micrograms per milliliter of DMSO in serum or plasma.
 - (10) The use of firocoxib shall be permitted under the following conditions: Not to exceed twenty (20)

nanograms per milliliter of firocoxib in serum or plasma.

- (11) The use of glycopyrrolate shall be permitted under the following conditions: Not to exceed three (3) picograms per milliliter of glycopyrrolate in serum or plasma.
- (12) The use of lidocaine shall be permitted under the following conditions: Not to exceed twenty (20) picograms per milliliter of total 3-hydroxylidocaine in serum or plasma.
- (13) The use of mepivacaine shall be permitted under the following conditions: Not to exceed ten (10) nanograms per milliliter of total 3-hydroxymepivacaine in urine or the LOD of mepivacaine in serum or plasma.
- (14) The use of methocarbamol shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of methocarbamol in serum or plasma.
- (15) The use of methylprednisolone shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of methylprednisolone in serum or plasma.
- (16) The use of omeprazole shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of omeprazole sulfide in urine.
- (17) The use of prednisolone shall be permitted under the following conditions: Not to exceed one (1) nanogram per milliliter of prednisolone in serum or plasma.
- (18) The use of procaine penicillin shall be permitted under the following conditions:
 - (A) Not to exceed twenty-five (25) nanograms per milliliter of procaine in serum or plasma, and
 - (B) Administration of procaine penicillin must be reported to the official veterinarian at the time of administration, and
 - (C) Procaine penicillin must not be administered after the horse is entered to race, and
 - (D) Mandatory surveillance of the horse must occur for the six (6) hours immediately preceding the race for which the horse is entered by association security at the owner's expense.
- (19) The use of triamcinolone acetonide shall be permitted under the following conditions: Not to exceed one hundred (100) picograms per milliliter of triamcinolone acetonide in serum or plasma.
- (20) The use of xylazine shall be permitted under the following conditions: Not to exceed one-hundredth (.01) of a nanogram per milliliter of xylazine in serum or plasma.

(Indiana Horse Racing Commission; <u>71 IAC 8.5-1-4.2</u>; emergency rule filed Jan 25, 2012, 12:20 p.m.: <u>20120201-IR-071120056ERA</u>; emergency rule filed Feb 8, 2012, 12:01 p.m.: <u>20120215-IR-071120072ERA</u>; emergency rule filed Apr 3, 2013, 10:37 a.m.: <u>20130410-IR-071130133ERA</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 11. 71 IAC 8.5-1-7.1 IS ADDED TO READ AS FOLLOWS

71 IAC 8.5-1-7.1 Multiple medication violations

Authority: <u>IC 4-31-3-9</u> Affected: <u>IC 4-31-12</u>

Sec. 7.1. (a) A trainer who receives a penalty for a medication violation based upon a horse testing positive for a Class 1-5 medication with Penalty Class A-D, as provided in the Uniform Classification Guidelines of Foreign Substances and Recommended Penalties and Model Rule as revised by the ARCI in August 1996 and any other subsequent revision effective after said date, which are incorporated by reference herein, may be assigned points based upon the medication's ARCI Penalty Guidelines as follows:

Class	Points if Controlled Therapeutic Substance	Points if Noncontrolled Substance
Class A	N/A	6
Class B	2	4
Class C	1	2
Class D	1/2	1

- (b) The points assigned to a medication violation shall be included in the stewards or commission ruling. Such ruling shall determine, in the case of multiple positive tests as described in paragraph [sic] (d), whether they shall thereafter constitute a single violation. The ruling shall be posted on the official website of the ARCI. If an appeal is pending, that fact shall be noted in the ruling. No points shall be applied until a final adjudication of the enforcement of any such violation.
 - (c) Once all appeals are waived or exhausted, the points shall immediately become part of the trainer's

official ARCI record and shall then subject the trainer to the mandatory enhanced penalties by the stewards or the commission as provided in this rule.

- (d) Multiple positive tests for the same medication incurred by a trainer prior to delivery of official notice by the commission may be treated as a single violation.
- (e) The official ARCI record shall constitute prima facie evidence of a trainer's past record of violations and cumulative points. Nothing in this section shall be construed to confer upon a trainer the right to appeal a violation for which all remedies have been exhausted or for which the appeal time has expired.
- (f) The stewards or commission shall include all points for violations in all racing jurisdictions as contained in the trainer's official ARCI record when determining whether the enhancements provided in this regulation shall be imposed.
- (g) In addition to the penalty for the underlying offense, the following enhancements may be imposed upon a licensed trainer based upon the cumulative points contained in the trainer's official ARCI record:

Points	Suspension in Days
3-5.5	30
6-8.5	60
9-10.5	180
11 or more	360

These points are intended to be an additional uniform penalty when the licensee:

- (1) has more than one violation for the relevant time period; and
- (2) exceeds the permissible number of points.
- (h) The suspension periods in [sic] (g) shall run consecutive to any suspension imposed for the underlying offense.
- (i) The stewards or commission ruling shall distinguish between the penalty for the underlying offense and the enhancement based upon the trainer's cumulative points.

(Indiana Horse Racing Commission; <u>71 IAC 8.5-1-7.1</u>; emergency rule filed May 7, 2014, 2:27 p.m.: <u>20140514-IR-071140143ERA</u>, eff May 15, 2014)

SECTION 12. 71 IAC 8.5-1-8 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8.5-1-8 Androgenic-anabolic steroids (AAS)

- Sec. 8. (a) No AAS (androgenic-anabolic steroid) shall be permitted in test samples collected from racing horses except for residues **endogenous concentrations** of the major metabolite of stanozolol, nandrolone, and the naturally occurring substances boldenone, **nandrolone**, and testosterone at concentrations less than the indicated thresholds.
- (b) Concentrations of these AAS shall not exceed the following urine threshold concentrations for total (i.e., free drug or metabolite and drug or metabolite liberated from its conjugates) **steroid:**
 - (1) 16# hydroxystanozolol (metabolite of stanozolol (Winstrol)) one (1) ng/ml in urine for all horses regardless of sex.
 - (2) (1) Boldenone: (Equipoise® is the undecylenate ester of boldenone)
 - (A) In male horse horses other than geldings fifteen (15) ng/mL in of urine. No boldenone shall be permitted in geldings or female horses.
 - (B) In geldings, fillies, and mares one (1) ng/mL of urine.
 - (3) (2) Nandrolone: (Durabolin® is the phenylpropionate ester and Deca-Durabolin® is the decanoate ester):
 (A) In geldings one (1) ng/mL in of urine.

- (B) In fillies and mares one (1) ng/mL in of urine.
- (C) In male horses other than geldings forty-five (45) ng/mL of nandrolone metabolite, 5#-oestrane-3#,17#-diol in 5#-estrane-3#,17#-diol of urine.
- (4) (3) Testosterone:
 - (A) In geldings twenty (20) ng/mL in of urine.
 - (B) In fillies and mares fifty-five (55) ng/mL of urine, unless in foal.
 - (C) In male horses other than geldings minimum thresholds will not apply.
- (c) Concentrations of these AAS shall not exceed the following free (i.e., not conjugated) steroid concentrations in plasma or serum:
 - (1) Boldenone: For all horses a confirmatory threshold not greater than 25 pg/mL shall apply.
 - (2) Nandrolone:
 - (A) In geldings, fillies, and mares a confirmatory threshold not greater than 25 pg/mL shall apply.
 - (B) In male horses other than geldings nandrolone shall be tested for in urine only.
 - (3) Testosterone:
 - (A) In geldings, fillies, and mares-- a confirmatory threshold not greater than 25 pg/mL.
 - (B) In male horses other than geldings minimum thresholds will not apply.
 - (e) (d) All other AAS are prohibited in racing horses.
 - (d) Post-race urine samples collected from intact males must be identified to the laboratory.
- (e) Any horse to which an anabolic steroid has been administered in order to assist in the recovery from illness or injury may be placed on the veterinarian's list in order to monitor the concentration of the drug or metabolite in urine. After the concentration has fallen below the designated threshold for the administered AAS, the horse is eligible to be removed from the list.
 - (f) Implementation of this rule shall commence April 1, 2008.
- (g) During the first ninety (90) calendar days of the first race meet beginning after the implementation date, no positive test establishing the presence of an anabolic steroid shall be considered a violation of this rule and, accordingly, shall not result in a penalty, disqualification, or a forfeiture of any purse, trophy, or award. Trainers shall be notified of any positive test during the ninety (90) day grace period.
 - (e) The sex of the horse must be identified to the laboratory for all samples designated for AAS testing.
- (f) A trainer may request that a horse be placed on the veterinarian's list due to medically necessary treatment with AAS. The horse shall remain on the veterinarian's list:
 - (1) for 365 days;
 - (2) until the concentration of the drug or metabolite in urine or blood has fallen below the designated threshold for the administered AAS; or
 - (3) until the concentration of the drug or metabolite in urine or blood has fallen below the limit of detection for AAS that do not have a designated threshold, whichever is longer.

(Indiana Horse Racing Commission; 71 IAC 8.5-1-8; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed May 12, 2008, 1:29 p.m.: 20080521-IR-071080353ERA; readopted filed Nov 26, 2013, 11:25 a.m.: 20131225-IR-071130345RFA; emergency rule filed May 7, 2014, 2:27 p.m.: 20140514-IR-071140143ERA, eff May 15, 2014)

SECTION 13. 71 IAC 8.5-2-5 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8.5-2-5 Out of competition testing

- Sec. 5. (a) Any horse eligible to race in Indiana under this subsection is subject to testing without advance notice for prohibited substances, practices, and procedures as specified in subsection (f), while the horse is located on the grounds of a racetrack under the jurisdiction of the commission, or stabled off association grounds while under the care or control of a trainer or owner licensed by the commission under the restrictions listed in subsection (e). A horse is eligible to race in Indiana if it is listed:
 - (1) on an owner's or trainer's license application; or
 - (2) a stall application, nomination list; or
 - (3) on the horse sign-in sheet at any time during the meet; or
 - (4) has raced at any Indiana race meet during the calendar year.

A horse shall be presumed eligible if it is a racing breed, at least two (2) years old and an Indiana bred or sired horse. The owner of such an Indiana bred or sired horse may render the horse ineligible for the testing as described in this regulation by indicating in writing the Indiana bred or sired horse is not intended to race in Indiana, pursuant to subsection (b) below provided that the owner of such an Indiana bred or sired horse provides such written notice to the office of the commission thirty (30) days before the horse turns two (2) years old or within thirty (30) days after the owner acquires the horse. In this event, the horse shall be deemed ineligible for racing in Indiana as provided for in subsection (b) below.

- (b) If a horse selected to be tested is not covered under subsection (a), the executive director or stewards may nevertheless test any such horse as eligible to race in Indiana for prohibited substances, practices, and procedures specified in subsection (f), unless the owner or trainer or other authorized representative or designee of such horse immediately represents in writing that the horse is not intended to be, and will not be, raced in Indiana for a minimum of three hundred sixty-five (365) days. If the owner, trainer, or other authorized representative or designee so represents, the horse shall be deemed ineligible for racing in Indiana for no less than three hundred sixty-five (365) days from that date. This three hundred sixty-five (365) day ineligibility to race in Indiana shall follow the horse even if sold or transferred to another owner or trainer. An owner or trainer may, however, consent to the collection of a sample from a horse selected for testing under this rule, even if the horse is not presently intended to be raced in Indiana, and if such horse tests negative, it will remain eligible to race in Indiana.
- (c) The executive director or stewards may order any horse of a licensed trainer to report to a track under the jurisdiction of the commission for out of competition testing. The trainer is responsible to have the horse or horses available at the designated time and location. In the event that a horse is ordered to report to a track pursuant to the authority granted by this subsection, a licensed trainer is entitled to reimbursement by the commission for mileage (at the current rate paid by the state of Indiana as specified in the current Indiana financial management circular) to and from the location where the horse was stabled when the horse was ordered to report to the track. Under no circumstances will a trainer be entitled to reimbursement for mileage in excess of the actual mileage to the track from the place where the horse was stabled when ordered to report and from the track to the place where the horse is first stabled following the testing. The trainer is not entitled to receive reimbursement from the commission for any other expense relating to any order under this subsection to report to a track for out-of-competition testing.
- (d) The official veterinarian, a licensed veterinarian authorized by the commission or a veterinary technician under the direct supervision of the official veterinarian, or a licensed veterinarian authorized by the commission may take a urine, blood, or hair sample from a horse for testing as provided for in this section.
- (e) Unless sample collection occurs on the grounds of a racetrack or other location within Indiana under the commission's jurisdiction, the commission's representatives must arrive for the taking of blood, urine, or hair samples from an eligible horse as defined in subsections [subsection] (a) or (b), only between the hours of 7:00 a.m. and noon, after announcing their presence at the premises where the horse(s) to be tested is (are) located and showing their credentials to collect samples from the horse(s) selected for testing for prohibited substances, practices, and procedures as specified in subsection (f). The commission's representatives or designees will request to meet with the trainer or owner of the selected horse(s). If neither is available, the collection will be deferred until the trainer and/or owner, or their representative or designee, becomes reasonably available, but the collection must occur not later than one (1) hour after the commission's designee arrives at the premises in the case of an eligible horse under subsection (a), and not later than two (2) hours in the case of an eligible horse under subsection does not occur within the time provided for in this subsection, any horse that would have been subject to testing and eligible to race in Indiana will be deemed to be ineligible for racing in Indiana pursuant to the provisions of subsections (a) and (b). In addition, the owner and/or trainer of the horses may be subject to any other sanctions allowed by Indiana law and regulations, including, but not limited to, a fine,

suspension, and/or summary suspension. It is a defense to any action brought against an owner and/or trainer for sanctions or as a result of any declaration a horse is ineligible because the sample collection did not occur within the time provided for by this subsection that good cause existed that prohibited the owner, trainer, and/or their representative or designee from complying with the time limits set forth in this subsection. The owner, trainer, and/or their representative or designee has the burden of proving the good cause defense by a preponderance of the evidence.

- (f) Prohibited substances, practices, and procedures are defined as the following:
- (1) blood doping agents including, but not limited to, erythropoietin (EPO), darbepoetin, Oxyglobin, Hemopure, Aranesp, or any substance that abnormally enhances the oxygenation of body tissues;
- (2) gene doping agents or the nontherapeutic use of genes, genetic elements, and/or cells that have the capacity to enhance athletic performance or produce analgesia;
- (3) naturally produced venoms, synthetic analogues of venoms, derivatives of venoms, or synthetic analogues of derivatives of venoms;
- (4) substances capable of producing a repartitioning effect that are not FDA-approved for use in horses, including, but not limited to, ractopamine, zilpaterol, or any similar agent;
- (5) AAS (androgenic-anabolic steroids) other than stanozolol, nandrolone, boldenone, testosterone and metabolites thereof; endogenous concentrations of the naturally occurring substances as defined in 71 IAC 8.5-1-8 or AAS in a horse placed on the veterinarian's list in accordance with 71 IAC 8.5-1-8(f); and (6) the presence in a horse of any substance at anytime listed in subdivision (f)(1), (f)(2), (f)(3), (f)(4), or (f)(5) [subdivision (1), (2), (3), (4), or (5)] in an eligible as defined in subsections (a) and (b) above is prohibited and is a violation of this rule.
- (g) The trainer and/or his/her designees shall cooperate with the official veterinarian, or any licensed veterinarian or licensed veterinary technician authorized by the commission, or any commission employee by:
 - (1) assisting in the immediate location and identification of the eligible horse selected for out of competition testing; and
 - (2) providing a stall or safe location to collect the samples.

The executive director or stewards may summarily suspend, exclude, and/or otherwise penalize any trainer and/or other authorized representative or designee who does not fully cooperate with a commission employee or representative in assisting and identifying an eligible horse or providing a safe stall to collect samples in a timely fashion. If any such person is summarily suspended, excluded, or otherwise penalized, she/he shall be entitled to a hearing in accordance with Indiana law and regulations. A summary suspension, exclusion, or sanctions for failure to cooperate shall not issue, however, if a horseman meets his or her burden to establish the good cause defense set forth under subsection (e). This provision does not apply to an owner or trainer who timely provides written notice under subsection (a) or (b) that a horse sought to be tested is not intended to be raced in Indiana and thereby renders the horse ineligible pursuant to subsection (b).

- (h) The collection of blood, urine, or hair samples under this rule shall be divided in three (3) parts to be analyzed as follows:
 - (1) approved primary laboratory for screening;
 - (2) approved primary laboratory for confirmation; and
 - (3) approved laboratory for split sample testing as chosen by the owner or trainer.

The commission shall approve the laboratories for screening, confirmation, and split sample testing.

(i) In the absence of extraordinary mitigating circumstances, a minimum penalty of a ten (10) year suspension will be assessed for any violation of subsection (f)(1) and (f)(2) of this rule [subsection (f)(1) and (f)(2)]. The Association of Racing Commissioners International, Inc. Uniform Classification Guidelines for Foreign Substances and Recommended Penalties and Model Rule will be considered for violations of (f)(3), (f)(4), and (f)(5)] with additional penalties for any drug not FDA approved for use in horses.

(Indiana Horse Racing Commission; 71 IAC 8.5-2-5; emergency rule filed Jul 23, 2007, 9:16 a.m.: 20070808-IR-071070461ERA, eff Jul 18, 2007 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #07-461(E) was filed with the Publisher July 23, 2007.]; errata filed Aug 14, 2007, 1:28 p.m.: 20070829-IR-071070461ACA; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.:

20110309-IR-071110100ERA; emergency rule filed Sep 10, 2012, 2:01 p.m.: 20120912-IR-071120525ERA; emergency rule filed May 7, 2014, 2:27 p.m.: 20140514-IR-071140143ERA, eff May 15, 2014)

SECTION 14. 71 IAC 8.5-5-2 IS AMENDED TO READ AS FOLLOWS:

71 IAC 8.5-5-2 Prohibited practices

Authority: <u>IC 4-31-3-9</u> Affected: <u>IC 4-31</u>

Sec. 2. (a) The possession and/or use of a drug, substance, or medication, specified below, on the premises of a facility under the jurisdiction of the commission is prohibited. The following drugs or substances include those which a recognized analytical method has not been developed to detect and confirm the administration of such substance, or the use of which may endanger the health and welfare of the horse or endanger the safety of the rider, or the use of which may adversely affect the integrity of racing:

- (1) Erythropoietin.
- (2) Darbepoietin.
- (2) Darbepoetin.
- (3) Oxyglobin.
- (4) Hemopure.
- (5) Snake venom.
- (6) Snail venom.
- (7) Ractopamine.
- (8) Zilpaterol.
- (b) The use of extracorporeal shock wave therapy or radial pulse wave therapy shall not be permitted unless the following conditions are met:
 - (1) Any treated horse shall not be permitted to race for a minimum of ten (10) days following treatment.
 - (2) The use of extracorporeal shock therapy or radial pulse wave therapy machines shall be limited to practicing veterinarians.
 - (3) Any extracorporeal shock therapy or radial pulse therapy machines on the association grounds must be registered with and approved by the commission or its designee before use.
 - (4) All extracorporeal shock therapy or radial pulse therapy treatments must be reported to the official veterinarian on the prescribed form not later than the time prescribed by the official veterinarian.
- (c) The possession and/or use of a drug, substance, or medication on the premises of a facility under the jurisdiction of the commission that has not been approved by the United States Food and Drug Administration (FDA) for any use (human or animal) is forbidden without prior permission of the commission. For purposes of this rule, the term "drug" is any substance, food or nonfood, that is used to treat, cure, mitigate, or prevent a disease, is any nonfood substance that is intended to affect the structure or function of the animal, and includes any substance administered by injection, **other than vaccines licensed by the USDA.**
- (d) While on the premises of a facility under the jurisdiction of the commission, veterinarians may only possess drugs, including compounds as discussed below in subsection (e), in amounts commensurate with the needs of horses with which the veterinarian has a veterinarian-client-patient relationship as that term is defined at 888 IAC 1.1-5-1(2).
- (e) Notwithstanding subsection (c), veterinarians may possess compounded drugs with the restrictions listed below. Compounding includes any manipulation of a drug beyond that stipulated on the drug label, including, but not limited to, mixing, diluting, concentrating, and/or creating oral suspensions or injectable solutions.
 - (1) Compounds may only be prescribed to or prepared for horses with which the veterinarian has a veterinarian-client-patient-relationship;
 - (2) Compounded drugs may only be made from other FDA-approved drugs;
 - (3) Veterinarians may not possess compounds where there are FDA-approved, commercially available drugs that can appropriately treat the horse; and
 - (4) Compounded drugs must be in containers that meet the prescription labeling requirements in subsections (i) and (j).

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- (f) The possession of any drug not approved by the FDA for distribution in the United States is prohibited, unless the veterinarian can show proof of prior authorization from the FDA Center for Veterinary Medicine that has been obtained on a single-patient basis only. The authorization must be maintained in the animal health record. A copy of the authorization must be available for immediate inspection.
- (g) Extra-label administration of drugs, including use for indication or at dosage levels, frequencies, or routes of administration other than those stated in the labeling, is permitted for FDA-approved drugs only. Extra-label use must meet the prescription labeling requirements in subsections (i) and (j).
- (h) A veterinarian shall not possess any drug that is not labeled pursuant to the requirements of subsection (i) or (j).
- (i) Drugs possessed by practicing veterinarians on the premises of a facility under the jurisdiction of the commission which have not yet been prescribed or dispensed to horses with which the veterinarian has a veterinarian-client-patient relationship must be affixed with the manufacturer's label which must include:
 - (1) recommended or usual dosage;
 - (2) route for administration, if it is not for oral use;
 - (3) quantity or proportion of each active ingredient;
 - (4) names of inactive ingredients, if for other than oral use;
 - (5) an identifying lot or control number;
 - (6) manufacturer, packer, or distributor's name and address; and
 - (7) net quantity contents.

If any information as described herein is not included on the manufacturer's label, but instead is on the manufacturer's package insert, the package insert must be maintained on the veterinarian's truck.

- (j) When issuing a prescription for or dispensing a drug to a horse with which the veterinarian has a veterinarian-client-patient relationship, the veterinarian must affix or cause to be affixed a label that sets forth the following:
 - (1) Name and address of the veterinarian;
 - (2) Name and address of the client:
 - (3) Name of the horse;
 - (4) Date of prescription and/or dispensing of drug;
 - (5) Directions for use, including dose and duration directions, and number of refills;
 - (6) Name and quantity of the drug (or drug preparation, including compounds) prescribed or dispensed;
 - (7) For compounded drugs, the established name of each active ingredient; and
 - (8) Any necessary cautionary statements.
- (k) The practice, administration, or application of a treatment, procedure, therapy, or method identified below, which is performed on the premises of a facility under jurisdiction of the commission or in any horse scheduled to compete in a race under the jurisdiction of the commission and which may endanger the health and welfare of the horse or endanger the safety of the rider or driver, or the use of which may adversely affect the integrity of racing is prohibited: Intermittent hypoxic treatment by external device.

(Indiana Horse Racing Commission; 71 IAC 8.5-5-2; emergency rule filed Aug 20, 2002, 3:00 p.m.: 26 IR 57; emergency rule filed Feb 21, 2003, 4:15 p.m.: 26 IR 2386; emergency rule filed Jan 21, 2004, 2:30 p.m.: 27 IR 1921; emergency rule filed Mar 10, 2006, 11:00 a.m.: 29 IR 2226; errata filed Apr 10, 2006, 2:00 p.m.: 29 IR 2546; emergency rule filed Mar 12, 2008, 1:53 p.m.: 20080326-IR-071080191ERA, eff Mar 11, 2008 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #08-191(E) was filed with the Publisher March 12, 2008.]; emergency rule filed Mar 19, 2009, 11:07 a.m.: 20090401-IR-071090195ERA, eff Mar 12, 2009 [IC 4-22-2-37.1] establishes the effectiveness of an emergency rule upon filing with the Publisher. LSA Document #09-195(E) was filed with the Publisher March 19, 2009.]; emergency rule filed Mar 3, 2011, 11:50 a.m.: 20110309-IR-071110100ERA; emergency rule filed May 7, 2014, 2:27 p.m.: 20140514-IR-071140143ERA, eff May 15, 2014)

SECTION 15. THE FOLLOWING ARE REPEALED: 71 IAC 8-1-5.7; 71 IAC 8.5-1-5.6.

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